

Research Ethics Office

Telephone: (416) 864-6060 Ext. 2557
Facsimile: (416) 864-6043
E-mail: pateld@smh.toronto.on.ca

St. Michael's

Inspired Care.
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April 19, 2010

Dr. Frances Silverman,
Department of Occupational and Environmental Health,
St Michael's Hospital

Dear Dr. Silverman,

Re: REB# 05-143 - Cardiovascular Toxicity of Concentrated Ambient Fine, Ultrafine and Coarse Particles in Controlled Human Exposures: Protocol #G4H10792 - Project 3

REB APPROVAL:	Original Approval Date	April 27, 2006
	Annual/Interval Review Date	April 27, 2011

Thank you for your communications dated **April 14, 2010** requesting an annual review and approval regarding the above named study.

This letter will serve as an extension of the St. Michael's Hospital (SMH) Research Ethics Board (REB) approval for the study for a period of 12 months effective from April 27, 2010 – April 27, 2011. Continuation beyond that date will require further review of REB approval.

During the course of this investigation, any significant deviations from the approved protocol and/or unanticipated developments or significant adverse events should immediately be brought to the attention of the REB.

The St. Michael's Hospital (SMH) Research Ethics Board (REB) operates in compliance with the Tri-Council Policy Statement Ethical Conduct for Research Involving Humans, the Ontario Personal Health Information Protection Act, 2004, and ICH Good Clinical Practice Consolidated Guideline E6, Health Canada Part C Division 5 of the Food and Drug Regulations, Part 4 of the Natural Health Product Regulations, and the Medical Devices regulations. Furthermore, all investigational drug trials at SMH are conducted by Qualified Investigators (as defined in the latter document).

Good luck with your investigations.

With best wishes

☐ Dr. Julie Spence
Chair, Research Ethics Board
JS/BJM/dk

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Dr. Brenda McDowell
Vice Chair, Research Ethics Board